

Sally A. Hunsberger

6700B Rockledge Dr Rm 5128 MSC 7630
Bethesda, MD 20892-7630
voice: (301)-451-2450
fax: (301)-480-0912

Education:

Ph.D., Biostatistics, Medical College of Virginia, VCU, Richmond, Virginia, December 1990.
Ph.D. dissertation "Semiparametric Regression in Likelihood Based Models."
B.A., Mathematics and Biology, Goshen College, Goshen, Indiana, May 1986.

Awards:

2006: Goshen College Champions of Character Award for those who have gone on to exemplify and demonstrate the core values of Goshen College.
1997: NIH Office of Equal Opportunity award for guiding the summer project of a stay in school student.
1994: NIH Merit Award for exceptional performance of statistical collaboration on clinical research programs in NHLBI.
1991: The Eastern North American Region Biometric Society Student Prize Award for best paper.
1986-1990: Medical College of Virginia, VCU, School of Graduate Studies Fellowship
1984, 1985: Academic All-American NAIA Tennis award

Professional Experience:

2013-present: Mathematical Statistician, Biometrics Research Branch, National Institute of Allergy and Infectious Diseases. Duties include: executive secretary for the Division of AIDS (DAIDS) complication and co-infection DSMB. Protocol review for DAIDS and the laboratory of clinical infectious disease. Statistical design and analysis for the Laboratory of infectious diseases and the laboratory of clinical infectious disease. Statistical partner for the La Red network which is a collaboration between NIH and Mexican ministry of health to study emerging infectious diseases.

2001-present: Member of Data Safety and Monitoring Committee for the Pediatric Heart Network, sponsored by the National Heart Lung and Blood Institute.

1999-2013: Mathematical Statistician, Biometrics Research Branch, National Cancer Institute. Duties included: Data Safety and Monitoring Committee member for the Children's Oncology Group (COG). National Surgical Adjuvant Breast and Bowel Project (NSABP), New Approaches to Neuroblastoma Treatment consortium (NANT) and, Pediatric Brain Tumor consortium (PBTC). Review Phase I, II and III cancer trial protocols. Develop Statistical procedures for Cancer research.

2006-2013: Member of the Data Safety and Monitoring Committee for the Gene and Cell therapy sponsored by the National Heart Lung and Blood Institute

1991-1999: Mathematical Statistician, Office of Biostatistics. National Heart, Lung and Blood Institute. Duties included: Consulting with intramural investigators at the NIH clinical center, performing statistical methodological research, participating in the design and analysis of large national multicentered clinical trials, and participating in DSMB discussions.

1998: One year sabbatical at St. Johns Medical college, Bangalore, India as a Biostatistics consultant.

1990: Medical College of Virginia, VCU. Instructor "Statistical Methods" course.

1986-1990: Medical College of Virginia, VCU, Graduate Research Assistant.

1987: Medical College of Virginia, VCU, Student Director Biostatistical Consulting Laboratory.

1985: Lovelace Biomedical and Environmental Research Institute, Summer Intern.

Professional Activities:

Member American Statistical Association and Biometric Society
Human Rights Committee member for the American Statistical Association (2009-2012).
Program Chair American Statistical Association meetings.
Organized Invited Session spring ENAR meetings (1997).
Program chair for Biostatistics and Public Health for the Washington Statistical Society.(1993-1995).
Referee for *Biometrics*, *Controlled Clinical Trials*, *Epidemiology*, *Journal of the National Cancer Institute*, *Journal of Clinical Oncology*, *Statistics in Medicine*, *Technometrics* and Article for Book "Statistics for Quality: Dedicated to DON OWEN", editors: Subir Ghosh, William R. Schucany, and William B. Smith.

Invited Presentations:

UHS-NIH Scientific Writing Workshop in Laos, 2015: "Overview of Study Designs" and "Writing the Results Section".

Goshen College, 2014: "Simple Approaches to Analyzing Self-Controlled Case Series (SCCS) Data".

ASCO International Clinical Trials workshop, Nepal, 2014: "Statistical Considerations in Clinical Trials".

Zhejiang International Symposium on the Progresses of Image Guided Radiation Therapy Conference, 2013: "Considerations of Clinical Trial Designs and Modern Image Guided Radiation Therapy".

Joint Statistical Meetings, August 2013: "Study Design Issues and Analysis Analysis of Error-prone Time to Event Data Using Progression Free Survival as an Example".

San Antonio Breast Cancer Symposium, December 2012. "When Should Studies be Randomized".

Virginia Commonwealth University, December 2011. "A Finite Mixture Survival Model to Characterize Risk Groups of Neuroblastoma".

Global Breast Cancer Conference, Seoul South Korea, October 2011. "Designs for Breast Cancer Studies in the Face of Changing Drug Development Issues" and "Seamless Phase II/III Designs for Breast Cancer Studies".

Annual Meeting of Korean Cancer Association, Seoul South Korea, June 2007. "Study design considerations for clinical trials of targeted agents" and "Progression-Free Survival in Unblinded Randomized Trials: A Proposal".

Joint Statistical Meetings, August 2006. "Testing Logistic Regression Coefficients with Clustered Data and Few Positive Outcomes".

Speaker in Education Session at ASCO May 2005: "Ethical and Clinical Dilemmas Resulting from the Early Closure of Recent Clinical Trials in Breast Cancer".

Discussant in Pediatric Oral Presentation session at ASCO May 2005.

Virginia Commonwealth University, Medical College of Virginia 1999: "A Test of Additivity in Semiparametric Regression using Kernel Smoothing." .

National Cancer Institute 1996: "A Test of Additivity in Semiparametric Regression using Kernel Smoothing."

Joint Statistical Meetings, Chicago 1996: "Imputation Strategies for Missing Data in a School Based Multicenter Study of American Indian Children: The Pathways Study."

Lecture Series sponsored by Division of Computer Research and Technology, National Institutes of Health 1993: "Designing Research Experiments an Iterative, Collaborative Process."

Publications

Hunsberger, S, and Poschan, MA (2016). "Simple approaches to analyzing self-controlled case series (SCCS) Data." *Statistics in Biopharmaceutical Research*

Godfrey, C., Tauscher G, Hunsberger, S, Austin, M, Scott, L, Schouten, J, Leutkemeyer, A, Benson, C, Coombs, R, and Swindells, S (2016). "A survey of tuberculosis infection control practices at the NIH/NIAID/DAIDS-supported clinical trial sites in low and middle income countries" *BMC Infectious Diseases* 1.

Colombo R, Fiorentino, Dodd, L, Hunsberger S, Haney, C, Barrett, K, Nabha, L, Davey, R and Olivier K (2016). "A phase 1 randomized, double-blind, placebo-controlled, crossover trial of DAS181 (Fludase) in adult subjects with well-controlled asthma." *BMC Infectious Diseases* 16.1 (2016): 1.

Ferre, Elise MN, et al. (2016). "Redefined clinical features and diagnostic criteria in autoimmune polyendocrinopathy-candidiasis-ectodermal dystrophy." *JCI Insight* 1.13.

Paulin-Prado, P, Nishimura, K, Freimanis-Harce L, Hunsberger S, et al (2016). "Clinical characteristics of asthmatic patients with influenza-like illness and risk of severe exacerbations in Mexico." *Annals of Allergy, Asthma & Immunology* 116.5 (2016): 402-407.

LoRusso PM et al. (2015). "Pilot trial of selecting molecularly guided therapy for patients iwth non-V600 BRAF mutant metastatic melanoma experience of the SU2C/MRA melanoma dream team." *Molecular Cancer Therapeutics* 1962-1971.

McShane, L and Hunsberger S (2015) "An Overview of phase II clinical trial designs with biomarkers" book chapter in *Design and Analysis of Clinical Trials for Predictive Medicine* 71-87. Shigeyuki Matsui, Marc Buyse and Richard Simon. (Editors) Chapman and Hall/CRC.

Hunsberger, S, Albert, PS and Thoma, M (2014). "Approaches to retrospective sampling for longitudinal transition regression model." *Statistics and its interface* 7.1 (2014): 75.

Schwandt A, Harris PJ, Hunsberger S, Deleporte A, Smith GL, Vulih D, Anderson BD and Ivy SP (2014). "The role of age on dose-limiting toxicities in phase I dose-escalation trials." *Clinical Cancer Research* 4768-4775.

Griffith, D, Adjemian, J, Brown-Elliott, Philley J, Prevots, R, Hunsberger S, Gaston C, Olivier K and Wallace R (2014) "The value of semi-quantitative mycobacterial cultures for predicting culture conversion during MAC lung disease therapy" *European Respiratory Journal* 246.

DeMichele, A, Berry, D., Zujewski, J, Hunsberger S, et. al. (2013). "Developing Safety Criteria for Introducing New Agents into Neoadjuvant Trials." *Clinical Cancer Research* 2817-2823.

Hunsberger, S (2012). "Phase II/III Designs" Chapter 12 in *Handbook of Statistics in Clinical Oncology, Third Edition*, Crowley J and Hoering A. (editors) CRC Press.

Takebe, N, Hunsberger, S and Yang, SX (2012). "Expression of GLi1 in the hedgehog signaling pathway and breast cancer recurrence." *Chinese Journal of Cancer Research* 24(4): 257-258.

- Gupta, Sachin, Hunsberger, S, Boerner, Scott; et al (2012). "Meta-Analysis of the relationship between dose and benefit in phase I targeted agent trials." *Journal of the National Cancer Institute* 104(24):1860–1866.
- Fay, MP and Hunsberger S (2012). "Practical issues on using weighted logrank tests with interval censored events in clinical trials" Chapter 13 in *Interval Censored Time-to-Event Data: Methods and Applications*, Chen, DG, Sun, J and Peace KE (editors) Chapman and Hall/CRC.
- Wang, M, Dignam, J, Zhang, QE, DeGroot, JF, Mehta, MP, Hunsberger S (2012). "Integrated Phase II/III clinical trials in oncology; A case study." *Clinical Trials* 9(6):741–747.
- LoRusso, PM, Boerner, S, Hunsberger S (2011). "Clinical Development of vascular disrupting agents: What lessons can we learn from ASA404?" *Journal of clinical Oncology* 29(22): 2952–2955.
- Smith, M., Devidas M., Wheatley, K, Lock RB and Hunsberger, S (2011). "Strategies for new agent development and clinical trial considerations" Chapter 8 in *Childhood Leukemia*, Reaman, GH and Smith FO (editors) Springer-Verlag.
- Hunsberger, S, Albert, PS and Dodd, L (2010). "Analysis of progression-free survival data using a discrete time survival model that incorporates measurements with and without diagnostic error." *Clinical Trials* 7(6): 634–642.
- Hunsberger, S, Zhao, Y, and Simon R (2010). "A comparison of phase II study strategies." *Clinical Cancer Research* 15(19): 5950–5955.
- Hunsberger, S, Albert, PS and London, WB (2009). "A finite mixture survival model to characterize risk groups of neuroblastoma." *Statistics in Medicine*, 28(8): 1301–1314
- McShane, LM, Hunsberger, S and Adjei, AA (2009). "Effective Incorporation of Biomarkers into Phase II Trials." *Clinical Cancer Research*, 15 (6), 1898–1905
- Ballard-Barbash R, Hunsberger, S, Alciati MH et al. (2009). "Physical activity, weight control and breast cancer risk and survival: clinical trial rationale and design considerations. " *Journal of the National Cancer Institute* 101(9): 630–643.
- Korn, EL, Hunsberger, S, Freidlin, B, Smith MA, and Abrams JS (2008). "Comments on 'Maintaining confidentiality of interim data to enhance trial integrity and credibility' by TR Fleming et al." *Clinical Trials* 5(4): 364–365.
- Hunsberger, S, Freidlin, B and Smith, MA (2008). "Complexities in interpretation of osteosarcoma clinical trial results." *Journal of Clinical Oncology* 26(18):3103–3104.
- Nathan PC, Whitcomb T, Wolters PL, Steinberg SM, Balis FM, Brouwers P, Hunsberger S, Feusner J, Sather H, Miser J, Odom LF, Poplack D, Reaman G, Bleyer WA (2006). "Very high-dose methotrexate (33.6 g/m²) as central nervous system preventive therapy for childhood acute lymphoblastic leukemia: results of National Cancer Institute/Children's Cancer Group trials CCG-191P, CCG-134P and CCG-144P." *Leukemia and Lymphoma* 47 (12): 2488–2504 DEC .
- Proschan MA, Hunsberger SA (2006). "Combining treatment selection and definitive testing". *Biometrical Journal* 48 (4): 690–692 AUG.
- Korn EL, Hunsberger S, Freidlin B, Smith MA, and Abrams JS (2005). "Preliminary data release for randomized clinical trials of noninferiority: a new proposal." *Journal of Clinical Oncology* , 23 (24): 5831–5836.

- Albert, P.S. and Hunsberger, S (2005). "On analyzing circadian rhythm data using non-linear mixed models with harmonic terms." *Biometrics*, 61 (4): 1115–1120.
- Korn EL, Rubinstein LV, Hunsberger SA, Pluda JM, Eisenhauer E and Arbuck SG (2005). "Clinical trial design for cytostatic agents and agents directed at novel molecular targets." In *Strategies for Discovery and Clinical Testing of Novel Anticancer Agents* (eds., A.A. Adjei and J. Buolamwini), Elsevier, 6: 003 Suppl.
- Rubinstein LV, Korn EL, Freidlin B, Hunsberger SA, Ivy SP, and Smith MA (2005). "Randomized phase 2 design issues and a proposal for phase 2 screening trials." *Journal of Clinical Oncology*, 23 (28): 7199–7206.
- Hunsberger S, Rubinstein LV, Dancey J, and Korn EL (2005). "Dose Escalation Trial Designs Based on a Molecularly Targeted Endpoint." *Statistics in Medicine*, 24:2171–2181 .
- Albert PS, Hunsberger SA, Hu N (2004). "Identifying multiple change points in heterogeneous binary data with an application to molecular genetics." *Biostatistics* 5(4):515–529.
- Lader E, Egan D, Hunsberger S, Garg R, Czajkowski S, McSherry F (2003). "The effect of digoxin on the quality of life in patients with heart failure." *Journal of Cardiac Failure* 9 (1): 4–12.
- Proschan MA, Liu Q, Hunsberger S (2003). "Proschan MA, Liu Q, Hunsberger S." *Controlled Clinical Trials* 24 (1): 4–15.
- Dorgan JF, Hunsberger SA. et al. (2003). "Diet and sex hormones in girls: Findings from a randomized controlled clinical trial." *Journal of the National Cancer Institute* 95 (2): 132–141.
- Hunsberger S, Albert PS, Follmann DA, Suh E (2002). "Parametric and semiparametric approaches to testing for seasonal trend in serial count data." *Biostatistics* 3 (2):289–298.
- Thompson B, Jacob RG, Frederick M, Geller NV, Hunsberger S (2002). "Innovative designs in behavioural trials." *Statistics in Medicine* 21 (19): 2981–2989.
- Philbin EF, Hunsberger S, Garg R, Lader E, Thadani U, McSherry F, Silver MA (2002). "Usefulness of clinical information to distinguish patients with normal from those with low ejection fractions in heart failure." *American Journal of Cardiology* 89 (10): 1218.
- Vaz M, Hunsberger S, Diffey B. (2002) "Prediction equations for handgrip strength in healthy Indian male and female subjects encompassing a wide age range." *Annals of Human Biology* 29 (2): 131–141
- Hunsberger, S., and Follmann D.(2001) "A Test of Additivity in Semiparametric Regression using Kernel Smoothing." *Statistics in Medicine* 20:1–19.
- Moss J, Avila NA, Barnes PM, Litzenberger RA, Bechtel J, Brooks PG, Hedin CJ, Hunsberger S, Kristof AS. (2001). "Prevalence and clinical characteristics of lymphangioleiomyomatosis (LAM) in patients with tuberous sclerosis complex." *American Journal of Respiratory and Critical Care Medicine* 164 (4): 669–671.
- Proschan MA, McMahon RP, Shih JH, Hunsberger SA, Geller NL, Knatterud G, Wittes J. (2001). "Sensitivity analysis using an imputation method for missing binary data in clinical trials." *Journal of Statistical Planning and Inference* 96 (1): 155–165 Sp. Iss. SI.
- Hunsberger, S., Davis, C.E., Murray, D., and Fabsitz, R. (2001). "Imputation Strategies for Missing Data in a School Based Multicenter Study of American Indian Children: The Pathways Study." *Statistics in Medicine* 20:305–316.

Obarzanek, E., Kimm S.Y., Barton, B.A., Van Horn, L., Kwiterovich, P.O., Simons-Morton, D.G., Hunsberger, S., Lasser, N.L., Robson, A.M., Franklin, F.A., Lauer, R.M., Stevens, V.J., Friedman, L.A., Dorgan, J.F., and Greenlick, M.R. (2001). "Long-Term Safety and Efficacy of a Cholesterol-Lowering Diet in Children: Seven-Year Results of the Dietary Intervention Study in Children(DISC)." *Pediatrics* 107:256-264.

Lohman, T.G., Caballero, B., Himes, J.H., Davis, C.E., Stewart, D., Houtkooper, L., Going, S.B., Hunsberger, S.A., Weber, J.L., Reid, R., and Stephenson, L (2000). "Estimation of Body Fat From Anthropometry and Bioelectrical Impedance in Native American Children." *International Journal of Obesity* 24:1-7.

Mathew, J., Hunsberger, S., Fleg, J., McSherry, F., Williford, W., and Yusuf, S (2000). "Incidence, Predictive Factors and Prognostic Significance of Supraventricular Tachyarrhythmias in Congestive Heart Failure". *Chest* 118:914-922.

Follmann, D. A., Hunsberger, and S., Albert, P.S. (1999) "Repeated Binary Regression When Covariates are Measured with Error." *Biometrics* 55:403-409.

Davis, C., Hunsberger S., Murray, D., Fabsitz, R., Himes, J., and Stephenson, L. (1999). "Design and Statistical Analysis for Pathways." *American Journal of Clinical Nutrition*, 69:(4) 760S-763S.

Lohman, T., Caballero, B., Himes, J., Hunsberger, S., Reid, R., and Stewart, D. (1999). "Body Composition Assessment in American Indian Children." *American Journal of Clinical Nutrition*, 69:(4) 764S-766S.

Going, S., Levin, S., Harrell, J., Stewart, D., Kushi, L., Cornell, C., Hunsberger, S., Corbin, C., and Sallis J. (1999). "Physical Activity Assessment in School-Age American Indian Children in the Pathways Study." *American Journal of Clinical Nutrition*, 69:(4) 788S-795S.

Thompson, B., Geller, N., Hunsberger, S., Fredrick, M., Hill, R., Kaufmann, P., Jacob, R.G., Freedman, R.R., Smith, E.A., Wigley, F.M., and Bielory, L. (1999). "Designing Clinical Trials When Interventions Require Different Treatment and Followup Methods: The Raynauds Treatment Study." *Controlled Clinical Trials*, 20:(1) 52-63.

Kwiterovich, P., Barton, B.A., McMahon, R., Obarzanek, E., Hunsberger, S., Simons-Morton, D., Kimm, S.Y.S., Friedman, L.A., Lasser, N., Robson, A., Lauer, Van Horn, L., R., Stevens, V., Gidding, S., Snetslaar, L., Hartmuller, V., and Franklin, F. (1998). "Effects of Dietary Cholesterol and Fat on LDL Cholesterol During Puberty: the dietary Intervention Study in Children(DISC)." *Circulation*, 98(8)2526-33.

Albert P.S., and Hunsberger S. (1997). "Modeling Repeated Measures With Monotonic Ordinal Responses and Misclassification: With Applications to Studying Maturation." *Journal of the American Statistical Association*, 1304-1312.

Obarzanek, E., Hunsberger, S., Barton, B., Franklin, F., Hartmuller, V., Kimm, S., Kwiterovich, P., Lauer, R., Stevens, V., and Van Horn, L. (1997). "Safety of a Fat-Reduced Diet in Growing Children:Dietary Intervention Study in Children(DISC)." *Pediatrics*, 51-59. Simons-Morton, D., Hunsberger, S., Van Horn, L., Barton, B., Robson, A., McMahon, R., Muhonen, L., Kwiterovich, P., Lasser, N., Kimm, S., and Greenlick, M. (1997). "Diet and Blood Pressure Relationships in Children: Dietary Intervention Study in Children." *Hypertension*, 29:930-6.

Toporoff, E.G., Simone, A.F., Story, M., Himes, J.H., Snyder, M.P., Dubray, M., Holy Rock, B., and Hunsberger, S. (1997). "Do Children Eat What They Say? Validity of Intended Food Choices Among Native American School Children." *Obesity Research*, 5(2)87-92.

Lazarous,D.F., Shou,M., Scheinowitz, M., Lobo, A., Kitsiou, A.N., Hunsberger, S.A, Epstein, S.E., and Unger, E.F. (1996). "Comparative Effects of Basic Fibroblast Growth Factor and Vascular Endothelial Growth Factor on Coronary Collateral Development and the Arterial Response to Injury in a Canine Model." *Circulation*, 94:1074-1082.

The Writing Group for the PEPI Trial (1996). "Effects of Hormone Therapy on Bone Mineral Density in the Spine and Hip: Results from the Postmenopausal Estrogen/Progestin Intervention (PEPI) Trial." *Journal of the American Medical Association*, 6:276(17):1430-1442

Lazarous,D.F., Scheinowitz, M., Shou,M., Hodge, E., Rajanayagam, S., Hunsberger, S., Robinson, W.G., Stiber, J.A., Correa, R., and Unger, E.F. (1995). "Effects of Chronic Systemic Administration of Basic Fibroblast Growth Factor on Collateral Development in the Canine Heart." *Circulation*, 91:145-153.

Proschan, M.A. and Hunsberger, S. (1995). "Extending Studies Based on Conditional Power." *Biometrics*, 51:1315-1324.

The Writing Group for the DISC Collaborative Research Group (1995). "Efficacy and Safety of Lowering dietary Intake of Fat and Cholesterol in Children with Elevated Low-density Lipoprotein Cholesterol: the Dietary Intervention Study in Children(DISC)." *Journal of the American Medical Association*, 273:1429-1435.

The Writing Group for the PEPI Trial (1995). "Effects of Estrogen or Estrogen/Progestin Regimens on Heart Disease Risk Factors in Postmenopausal Women." *The Journal of the American Medical Association*, 273:199-206.

Hunsberger, S.A. (1994). "Semiparametric Regression in Likelihood Based Models." *Journal of the American Statistical Association*, 89:1354-1365.

Hunsberger, S., Sorlie, P., and Geller, N. (1994). "Stochastic Curtailing and Conditional Power in Matched Case-Control Studies." *Statistics in Medicine* 13:663-670.

Mautner, G.C., Mautner, S.L., Cannon R.O., Hunsberger, S.A., and Roberts, W.C. (1994). "Clinical Factors Useful in Predicting Aortic Valve Structure in Patients >40 Years of Age with Isolated Valvular Stenosis." *American Journal of Cardiology*, 72(2):194-8.

Wu, M.C., Hunsberger, S.A., and Zucker D. (1994). "Testing for Differences in Changes in the Presence of Censoring: Semiparametric Versus Parametric and Nonparametric Methods." *Statistics in Medicine*, 13:635-646.

Abassi, Z.A., Tate, J., Hunsberger, S.A., Klein, H., Trachewsky, D., and Keiser, H.R. (1992). "Pharmacokinetics of ANF and Urodilatin During c-ANF Receptor Blockade and Neutral Endopeptidase Inhibition." *American Journal of Physiology*, 263:E870-E876.

Mautner, S.L., Mautner, G.C., Hunsberger, S.A., and Roberts, W.C. (1992). "Comparison of Composition of Atherosclerotic Plaques in Saphenous Vein used as Aortocoronary Bypass Conduits with Plaques in Native Coronary Arteries in the Same Men." *The American Journal of Cardiology*, 70:1380-1387.

Armstrong C.W., Mayhall C.G., Miller K.B., Newsome H.H. Jr., Sugarman H.J., Dalton H.P., Hall G.O., and Hunsberger S.A. (1990). "Clinical Predictors of Infection of Central Venous Catheters used for Total Parenteral Nutrition." *Infection Control and Hospital Epidemiology*, 11(2):71-78.

Medinsky, M.A., Bond, J.A., and Hunsberger, S.A. (1989). "A Physiologically Based Model of 1-nitropyrene Metabolism After Inhalation or Ingestion." *Health Physics*, 57(1):149-155.

Medinsky, M.A., Bond, J.A., Hunsberger, S.A., and Sun, J.D. (1988). "Lung, Liver, and Kidney as Potential Target Organs After Exposure to 1-Nitropyrene, as Determined by the Time Course of Covalently Bound Material." *Journal of Toxicological Environmental Health*, 23(4):445-454.